WE CLAIM:

1. An oral solid dose rapidly disintegrating nanoparticulate formulation comprising:

(a) a solid dose matrix comprising at least one pharmaceutically acceptable water-soluble or water-dispersible excipient, and

(b) within the solid dose matrix a nanoparticulate active agent composition comprising:

(i) a poorly soluble active agent having an effective average particle size of less than about 2000 nm prior to inclusion in the dosage form; and

(ii) at least one surface stabilizer adsorbed on the surface of the active agent;

wherein the solid dose matrix surrounding the nanoparticulate active agent and at least one surface stabilizer substantially completely disintegrates or dissolves upon contact with saliva is less than about 3 minutes.

2. The composition of claim 1, wherein the effective average particle size of the active agent particles is selected from the group consisting of less than about 1500 nm, less than about 1000 nm, 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

3. The composition of claim 1, wherein the solid dose matrix substantially completely disintegrates or dissolves upon contact with saliva in a time period selected from the group consisting of less than about 2 minutes, less than about 90 seconds, less than about 60 seconds, less than about 45 seconds, less than about 30 seconds, less than about 20 seconds, less than about 15 seconds, less than about 10 seconds, and less than about 5 seconds.

4. The composition of claim 1, wherein the concentration of the active agent is from about 0.1% to about 99.9% (w/w).

5. The composition of claim 4, wherein the concentration of the active agent is from about 5% to about 70% (w/w).

6. The composition of claim 5, wherein the concentration of the active agent is from about 15% to about 40% (w/w).

7. The composition of claim 1, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 99.9% to about 0.1% (w/w).

8. The composition of claim 7, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 95% to about 30% (w/w).

9. The composition of claim 8, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 85% to about 60% (w/w).

10. The composition of claim 1, wherein said at least one pharmaceutically acceptable water-soluble or water-dispersible excipient is selected from the group consisting of a sugar, a sugar alcohol, a starch, a natural gum, a natural polymer, a synthetic derivative of a natural polymer, a synthetic polymer, and mixtures thereof.

11. The composition of claim 10, wherein said at least one pharmaceutically acceptable water-soluble or water-dispersible excipient is selected from the group consisting of sucrose, maltose, dextrates, dextrin, guar gum, polydextrose, tragacanth, carbomers, cellulose-based polymers, lactose, glucose, mannose, mannitol, sorbitol, xylitol, erythritol, lactitol, maltitol, corn starch, potato starch, maize starch, gelatin, carrageenin, acacia, xanthan gum, an alginate, dextran, maltodextran, polyethylene glycol, polyvinylpyrrolidone, polyvinylalcohol, polyoxyethylene copolymers, polyoxypropylene copolymers, polyethyleneoxide, and a mixture thereof.

12. The composition of claim 10, wherein said excipient is selected from the group consisting of a direct compression material and a non-direct compression material.

13. The composition of claim 12, wherein said excipient is selected from the group consisting of a spray-dried mannitol and spray-dried lactose.

14. The composition of claim 1, wherein the solid dose formulation is made by fluid bed granulation, spray drying, or high shear granulation.

15. The composition of claim 1 further comprising at least one effervescent agent.

16. The composition of claim 1, wherein said composition has been lyophilized.

17. The composition of claim 1, wherein the poorly soluble active agent is in the form of crystalline particles, semi-crystalline particles, amorphous particles, or a mixture thereof.

18. A method of preparing an oral solid dose rapidly disintegrating nanoparticulate formulation comprising:

(a) combining (i) a nanoparticulate composition of a poorly soluble active agent and at least one surface stabilizer adsorbed to the surface thereof, wherein the active agent has an effective average particle size of less than about 2000 nm, and (ii) at least one pharmaceutically acceptable water-dispersible or water-soluble excipient, which forms a solid dose matrix surrounding the nanoparticulate composition; and

(b) forming a solid dose formulation,

wherein the solid dose matrix surrounding the nanoparticulate active agent and surface stabilizer substantially completely disintegrates or dissolves upon contact with saliva is less than about 3 minutes.

19. The method of claim 18, wherein the effective average particle size of the active agent particles is selected from the group consisting of less than about 1500 nm, less than about 1000 nm, 600 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

20. The method of claim 18, wherein the solid dose matrix substantially completely disintegrates or dissolves upon contact with saliva in a time period selected from the group consisting of less than about 2 minutes, less than about 90 seconds, less than about 60 seconds, less than about 45 seconds, less than about 30 seconds, less than about 20 seconds, less than about 15 seconds, less than about 10 seconds, and less than about 5 seconds.

21. The method of claim 18, wherein the nanoparticulate composition and the at least one water-dispersible or pharmaceutically acceptable water-soluble excipient are combined in step (a) using a method selected from the group consisting of:

(i) fluid bed granulation to form granules of the nanoparticulate composition and at least one water-soluble or water-dispersible excipient,

(ii) spray drying to form particles of the nanoparticulate composition and at least one water-soluble or water-dispersible excipient; and

(iii) high shear granulation to form granules of the nanoparticulate composition and at least one water-soluble or water-dispersible excipient;

which are then compressed in step (b) to form a solid dose formulation.

22. The method of claim 21, comprising adding one or more additional pharmaceutically acceptable water-soluble or water-dispersible excipients to the granules or particles formed in (i), (ii), or (iii) in step (a) prior to compression of the granules in step (b) to form a solid dose formulation.

23. The method of claim 18 wherein step (b) comprises compression of the composition formed in step (a).

24. The method of claim 18 wherein step (b) comprises lyophilization of the composition formed in step (a).

25. The method of claim 18 additionally comprising adding at least one effervescent agent to the composition prior to step (b).

26. A method of treating a mammal comprising administering to the mammal an effective amount of a solid dose rapidly disintegrating nanoparticulate formulation wherein:

(a) the formulation comprises a solid dose matrix comprising at least one pharmaceutically acceptable water-soluble or water-dispersible excipient, and

(b) within the solid dose matrix a nanoparticulate active agent composition comprising:

(i) a poorly soluble active agent having an effective average particle size of less than about 2000 nm prior to inclusion in the dosage form; and

(ii) at least one surface stabilizer adsorbed on the surface of the active agent;

wherein the solid dose matrix surrounding the nanoparticulate active agent and surface stabilizer substantially completely disintegrates or dissolves upon contact with saliva is less than about 3 minutes.